

REMARKS

Claims 1-54 are pending in the application. Claims 6-9, 15 and 16 are withdrawn from consideration.

Claim 1 section (e) has been amended. Support for the amendment can be found in the Specification on pages 9-10 and the Sequence Listing.

Claims 23 and 32 have been amended to be independent, incorporating all of the limitations of the claims upon which they previously depended.

New claim 55 has been added. Support for the claim can be found in claim 1.

No new matter has been added.

Objections

The Examiner has objected to claims 23, 32, 34, 36, 46, 48 and 50 as depending from rejected claims, but states that these claim would be allowable if written in independent form.

Applicants have amended claims 23, 32 and 34 to be in independent form. Claims 34, 36, 46, 48 and 50 depend from these. Consequently, Applicants submit that claims 23, 32, 34, 36, 46, 48 and 50 are allowable.

Rejections Under 35 USC § 112, First Paragraph

The Examiner has rejected claims 1-5, 10-14, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51 and 53 for lack of Written Description. The Examiner's rejections can essentially be summarized as being directed to section (e) of claim 1. The Examiner contends that the Specification does not disclose that only the first 100 amino acids are crucial to branching enzyme function and does not describe which features of the first 100 amino acids are critical for the invention. Applicants respectively traverse.

Applicants have amended section (e) to include those regions of the protein that must be present. Thus, a structure-function correlation is present and the claim meets the written description requirement. Therefore, Applicants respectfully request reconsideration and removal of the rejection.

Double Patenting – Obviousness-type

The Examiner has rejected claims 1-5, 10-14, 17-22, 24-30, 37-44 and 51-54 on the basis of nonstatutory obviousness-type double patenting as unpatentable over claims 1, 3, 4, 6, 8, 11, 13, 15 and 17 of US Patent No. 6,566,585 ('585). The Examiner states that Applicants' arguments that there would be no extension of patent term are not persuasive" because the granting of more than one patent for the same invention is prohibited under patent law." Applicants respectfully traverse.

Applicants first point out that the instantly claimed invention is not "the same invention" as the invention claimed in the '585 patent. According to the Manual of Patent Examining Procedure (MPEP), Eighth Edition, Latest Revision July 2008, § 804 (II), the "same invention" means identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1984); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957). A reliable test for double patenting under 35 USC § 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. That is not the case here. The claims of the '585 patent are directed to a transgenic plant cell which is genetically modified by introducing a foreign nucleic acid molecule or several foreign nucleic acid molecules encoding a branching enzyme *and an amylosucrase protein from Neisseria* while the claims of the instant application are directed to one particular branching enzyme.

Applicants again point out that the term of a patent issuing from the instant application will expire before the '585 patent. The MPEP §804 (II) (B) states

“A rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper **timewise** extension of the right to exclude granted by a patent.”
(emphasis added)

The Examiner also alleges that the ‘585 patent renders the instant claims obvious “because the genus is narrow, i.e. a branching enzyme from a particular species; and in this case, the only disclosed embodiment of the issued patent is SEQ ID NO:1...” Again, Applicants respectfully traverse.

MPEP §804 (II) (B) (1) states

“In determining whether a nonstatutory basis exists for double patenting rejection, the first question to be asked is – does any claim in the application define an invention that is anticipated by, or is merely an obvious variation of, an invention **claimed** in the patent? If the answer is yes, then an ‘obviousness-type’ nonstatutory double patenting rejection may be appropriate. Obviousness-type double patenting requires *rejection of an **application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent*** ...when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. See *Eli Lilly & Co. v Barr Labs., Inc.*, 251 F.3d 955, 58 USPQ2d 1869 (Fed. Cir. 2001); *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000).” (emphasis added)

The claims of the present application are not anticipated by the claims of the ‘585 patent. Double patenting rejections must be based on the language of the **claims** in the patent; the patent disclosure may not be used as prior art. *In re Vogel and Vogel*, 164 USPQ 619, 622 (CCPA 1970). As stated by MPEP § 804 (II) (B) (1)

When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. *General Foods Corp. v Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992)

The claims in the instant invention are directed to one particular branching enzyme nucleic acid sequence while the claims of the '585 patent are directed to a transgenic plant cell which is genetically modified by introducing a foreign nucleic acid molecule or several foreign nucleic acid molecules encoding a branching enzyme *and an amylosucrase protein from Neisseria*. These are not obvious variants of one another.

With respect to the Examiner's statement "the genus is narrow, i.e. a branching enzyme from a particular species; and in this case, the only disclosed embodiment of the issued patent is SEQ ID NO:1..." it bears repeating that the *patent disclosure may not be used as prior art*. *Id.* Furthermore, the claims of '585 should be taken as a whole when analyzing and deciding a double patenting issue: it is improper to look at one isolated feature of the claim only. In the *General Foods Corp. v Studiengesellschaft Kohle mbH* case the court has held that "Claims must be read as a whole in analyzing a claim of double patenting." *Id.* The court also held that "double patenting is based entirely on what is claimed, reading each claim as an entirety to determine what invention it defines. *Id.* Importantly, the court held that the disclosure of a patent cited in support of a double patenting rejection cannot be used as though it were prior art, even where the disclosure is found in the claims; there is a distinction between a claim as a written disclosure and a claim as a definition of an invention. *Id.* The Examiner is encouraged to review the synopsis of the *General Foods Corp. v Studiengesellschaft Kohle mbH* case that is presented in Appendix A.

Moreover, and contrary to the Examiner's statements, the genus of branching enzymes disclosed in the '585 patent is large and includes all branching enzymes. Currently there

are 3356 entries in GenBank for 1,4-alpha-glucan branching enzymes. Furthermore, many embodiments of suitable branching enzymes from plants, bacteria, algae and fungi (see column 5, lines 38-61) are presented in the '585 Specification. Still further, the '585 patent claims do not disclose the specific sequence of the branching enzyme claimed in the present application and are not directed to that nucleotide. Again, a double patenting rejection must be based on the language of the claims in the patent.

To summarize, none of the '585 claims are infringed by someone who uses an isolated nucleic acid molecule encoding a branching enzyme from Neisseria, or a host cell transformed with said nucleic acid molecule. So there is no extension of patent protection of US 6,566,585, even if a patent issuing from the instant application had a term which expired later than that of '858, which it does not. In addition, the instantly claimed invention is not obvious over the subject matter of the invention claimed in '585. As a consequence, the instant claims are both novel and unobvious over the '585 application.

In view of the above, Applicants submit that the obviousness-type double patenting rejection is improper and therefore respectfully request removal of the rejection.

Conclusion

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Susan W. Gorman, Reg. No. 47,604 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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Enclosures: Appendix A

APPENDIX A

Excerpts from *General Foods Corp. v Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992)

US Patent 3,806,619, issued April 23, 1974

1. A process for obtaining caffeine from green coffee which comprises:

- a) contacting moist carbon dioxide in supercritical state with the coffee in a caffeine absorption zone for absorption of caffeine by the moist carbon dioxide,
- b) withdrawing the moist carbon dioxide containing absorbed caffeine from the absorption zone and contacting it with water for extraction of caffeine from the moist carbon dioxide in an extraction zone for formation of an aqueous solution of caffeine,
- c) recirculating the moist carbon dioxide between the absorption zone and the contacting zone,
- d) withdrawing aqueous solution of carbon dioxide from the extracting zone and introducing it into an evaporating zone, passing a stream of air or nitrogen through the aqueous solution in the evaporating zone for evaporation of water from the solution and concentration of caffeine in the aqueous solution, and withdrawing a concentrated aqueous solution from the evaporating zone,
- e) withdrawing the air or nitrogen laden with water vapor from the evaporating zone and cooling it for condensation of water and separating the water from the air or nitrogen in a separating zone,
- f) recirculating the air or nitrogen between the evaporating zone and the separating zone,
- g) admixing aqueous solution of carbon dioxide from the extraction zone with the air or nitrogen conveyed from the separating zone to the evaporating zone,
- h) passing the air or nitrogen laden with water vapor and the admixture formed in step (g) in indirect heat exchange relation between the evaporating zone and the separating zone, for cooling of the air or nitrogen laden with water vapor for the

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condensation of step (e) and heating said admixture for heating the aqueous solution for the evaporation, and

[no step i.]

j) supplying additional heat to the aqueous solution for the evaporation.

US Patent 4,260,639, issued April 7, 1981

1. A process for the decaffeination of raw coffee which comprises contacting the raw coffee with water-moist carbon dioxide above its critical temperature and critical pressure to effect removal of caffeine therefrom and recovering a substantially decaffeinated coffee, the amount of water in the carbon dioxide being sufficient to effectuate said removal of the caffeine from the coffee.

Claim 1 of the '619 patent was the sole basis of an ultimate double patenting holding of the trial court, whose conclusions read:

24. For all the foregoing reasons, we find that claim 1 of the decaffeination patent ['639] is obvious from claim 1(a) of the caffeine recovery patent ['619]. Consequently, plaintiff is entitled to a judgment declaring claim 1 of the decaffeination patent invalid on the ground of obviousness-type double patenting.

69. Claim 1(a) of the '619 patent anticipates, or at least renders obvious, the inventions of claims 1 and 4 of the '639 patent because every step of claims 1 and 4 of the '639 patent is set forth in claim 1(a) of the '619 patent....

The CAFC has overruled the trial court's decision by applying the following reasons:

49. Double patenting is altogether a matter of what is claimed. Claim interpretation is a question of law which we review de novo. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861,

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228 USPQ 90 (Fed.Cir.1985). As we construe the claims here involved, claims 1 and 4 of the patent in suit, '639, define a process of decaffeinating raw coffee with supercritical water-moist carbon dioxide and recovering the decaffeinated coffee. They say nothing about what happens to the caffeine. Claim 1 of the '619 patent, relied on to show double patenting, defines a 9-step process of "obtaining caffeine from green coffee." Anything less than a process with all 9 steps is not what is claimed, and is, therefore, not patented. Claims must be read as a whole in analyzing a claim of double patenting.

(...)

69. The basic concept of double patenting is that the same invention cannot be patented more than once, which, if it happened, would result in a second patent which would expire some time after the original patent and extend the protection timewise. But double patenting law has always been more inclusive. Double patenting law principles extend to merely obvious variants of what has been patented. Step one of the analysis is to determine what that is. Claims are the determinants.

(...)

71. It should suffice, we feel, to point out the principal error into which the trial court was led which resides in a complete misinterpretation of claim 1, set forth above, of the '619 patent on the caffeine recovery process, now expired. We have quoted above, immediately following claim 1 of the '619 patent, Conclusion of Law 24 which is the ultimate error. The gist of it is that claim 1 of patent '639 in suit is "obvious from claim 1(a)" of patent '619. Of course, there is no such thing as "claim 1(a)," a term used no less than 11 times throughout the Findings of Fact and Conclusions of Law. There is a claim 1 and the first step of its 9 recited steps is designated "(a)." And that step recites the essence of the very same process claimed in the '639 patent in suit but, in accordance with the principles of claim construction discussed early in this opinion, step (a) is not "claimed" in the '619 patent, nor is it "patented" or "covered" as the trial court seems to have thought it was as shown by its Finding of Fact 58 which says: *"It was obvious to one of ordinary skill in the art that supercritical carbon dioxide would substantially decaffeinate*

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coffee, as otherwise it would not be claimed in claim 1 of the '619 patent...." (Emphasis ours.) This concept violates the fundamental rule of claim construction, that what is claimed is what is defined by the claim taken as a whole, every claim limitation (here each step) being material. What is patented by claim 1 of '619 is a 9-step caffeine recovery process, nothing more and nothing less.

72. A further error of the trial court in dealing with the '619 patent's claim I was in looking, not at what invention it defines, but at whatever the claim discloses, illustrated by Findings of Fact 68 and 69.

73. [68] *There cannot be double patenting here unless the plaintiff [GF] establishes, inter alia, that claims 1 and 4 of the '639 patent are obvious from the claims of the '619 patent, as interpreted by the specification in view of the prior art.*

74. This is perfectly sound law if one construes "from the claims" to mean from the invention defined by the claims, but in the next finding the court jumps the track (emphasis ours):

75. [69] *Claim 1(a) of the '619 patent anticipates, or at least renders obvious, the inventions of claims 1 and 4 of the '639 patent because every step of claims 1 and 4 of the '639 patent is set forth in claim 1(a) of the '619 patent....*

76. This clearly is using nothing but the disclosure of clause (a) of claim 1 as though it were prior art, and in not reading claim 1 to determine what invention it defines--like the metes and bounds of a deed. We repeat, clause (a) of claim 1 is not a claim, patent '619 does not claim clause (a) but a 9-step process of which (a) is the first step, and double patenting is based entirely on what is claimed, reading each claim as an entirety to determine what invention it defines.

77. A further illustration of the same misconstruction of claims by reading them for what they disclose rather than to determine what they define appears in Conclusion of Law 18 which says, in part, *"in this case the only relevant inquiry is whether the claims of the first patent 'disclose [] to one of ordinary skill in the art' the claims of the second patent."* (Emphasis ours.) The source of the quoted phrase is not given. The court failed to

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observe the distinction between a claim as a written disclosure and a claim as a definition of an invention.

80. Our precedent makes clear that the disclosure of a patent cited support of a double patenting rejection cannot be used as though it were prior art, even where the disclosure is found in the claims (...)

(...)

93. Since a patent is not infringed unless one or more claims are infringed and none of the '619 claims are infringed by one practicing the decaffeination process claimed in patent '639 without more, the '619 patent did not cover the '639 process and a patent thereon cannot extend the protection granted by the now expired '619 patent.